COPE II-study.

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A self-management program including self-treatment of exacerbations, leads to a reduction in the severity and duration of exacerbation compared to a similar self-management program without these self-treatment guidelines in hospital out-patients...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24374

Bron
Nationaal Trial Register

Verkorte titel
COPE II

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Effect of self-treatment within a self-management program:
Duration and severity of the exacerbations
Measured by daily diaries which are filled out by all the patients during the total length of the study;

2. Effect of an exercise program within a self-management program:
Functional exercise capacity:
Shuttle Walk Test.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:
Chronic Obstructive Pulmonary Disease (COPD) is a serious health problem. Efficacy of therapies is often limited or unknown. Effects of self-management programs are inconclusive.
Purpose of the study:
This study evaluates effects of two independent interventions within a self-management program: self-treatment of exacerbations and a physical exercise program (COPE-active). These programs will be compared with identical programs without the interventions.
Population:
200 COPD patients with 25 - 80% FEV1% predicted and „d 3 exacerbations or one hospitalization in the two years prior to study.
Methods:
Smokers are offered an smoking cessation program prior to the study. Patients are balanced into four groups.
All patients receive small-group self-management education given by respiratory nurses and physiotherapists. Contents are: the disease, exacerbations, nutrition, medication, relaxation and breathing exercises. Patients within the groups A1 and A2 get individual guidelines for self-treatment of exacerbations. Finally, patients (A1 and B1) are obliged to participate in the COPE-active program for a minimum of six months (maximum of eleven months).
Primary endpoints: severity and duration of exacerbations and functional exercise capacity.
Secondary endpoints: quality of life, health status, self-efficacy, activity at home, lung function, Fat Free Mass, and costs. Every 6-month period a measurement will be done.
The inclusion of patients has started in November 2004. Inclusion will end in June 2006. Data will be analyzed by means of repeated measurements analyses. A cost-effectiveness analysis will also be performed.

Doel van het onderzoek

A self-management program including self-treatment of exacerbations, leads to a reduction in the severity and duration of exacerbation compared to a similar self-management program without these self-treatment guidelines in hospital out-patients with COPD after one year and after two years.

A self-management program including a COPE-active program, has an additional effect on functional exercise performance compared to a similar program without this COPE-active program in hospital out-patients with COPD after one year and after to years.

Onderzoeksproduct en/of interventie

The study will be divided into two periods. During the first three-month period, smokers motivated to quit are offered an intensive smoking cessation program. In the second phase, all patients will be ordered over four groups: A1, A2, B1 and B2, according to a two by two factorial design.
The division of 200 patients over the four study groups will be done with the help of a balancing program. Potential confounders such as smoking status, gender, lung function,

participation in physiotherapy programs and the use of inhaled corticosteroids will be balanced over the four groups.
After division, all patients will receive a self-management program (four group sessions of two hours and several phone calls made by a respiratory nurse). During the self-management program, only the patients in the groups A1 and B1 will learn to treat themselves in case of an exacerbation. This will be done with help of individual guidelines for self-treatment of exacerbations (action plans). After the last group session of the self-management program, patients in the groups A1 and B1 will be obliged to participate in an intensive physical exercise program (COPE-active) program for six months, which can be continued until a maximum of eleven months.

Contactpersonen

Publiek

Medisch Spectrum Twente,
P.O. Box 50000

J. Palen, van der
Enschede 7500 KA
The Netherlands
+31 (0)53 4872023

Wetenschappelijk

Medisch Spectrum Twente,
P.O. Box 50000

J. Palen, van der
Enschede 7500 KA
The Netherlands
+31 (0)53 4872023

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. FEV1 between 25% and 80% of the predicted value;
2. Three or more exacerbations or one hospitalization in the two years preceding study entry;
3. A signed and dated written informed consent from the subject prior to study participation;

4. Patients of the outpatient clinic of the Medisch Spectrum Twente;
5. Age between 40 and 75 years;
6. A clinical diagnosis of COPD as defined by the GOLD-criteria (9);
7. Stable and well controlled COPD, at least one month before inclusion;
8. Current smoker or ex-smoker;
9. Able to understand, read and write Dutch.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Serious other disease with a low survival rate;
2. Other disease which influences bronchial symptoms and/or lung function (e.g. cardiac insufficiency, sarcoïdosis);
3. Severe psychiatric illness;
4. A disregulation of diabetes mellitus during an exacerbation in the past or a hospitalization for diabetes mellitus in the two years preceding the study;
5. Need for regular oxygen therapy;
6. Maintenance therapy with antibiotics;
7. Known alpha1 antitrypsine deficiency;
8. Disorders or progressive diseases, which influence seriously the ability to walk (e.g. amputation, paralysis, progressive muscle diseases).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2004
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL287
NTR-old	NTR325
Ander register	: Astma Fonds: 3.4.02.12; MEC:P04-13
ISRCTN	ISRCTN81447311

Resultaten

Samenvatting resultaten
N/A